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| 09/691,051      | 10/19/2000  | Ronald P. Lesser     | P 268412 DM-3580    | 5363             |

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PILLSBURY WINTHROP, LLP  
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EXAMINER

OROPEZA, FRANCES P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3762

DATE MAILED: 08/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/691,051

Applicant(s)

LESSER ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3/3/03 (Amendment) & 6/16/03 (Election).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35-60 is/are pending in the application.
- 4a) Of the above claim(s) 47, 48 and 50-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-46 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Election/Restrictions filed 6/16/03***

1. Claims 47, 48 and 50-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/ species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No.12.

The Applicant's arguments regarding the election/ restriction filed 6/16/03 have been fully considered.

The restrictions to three different inventions is deemed proper as Group I. is drawn to a method to treating a medical disorder, Group II. is drawn to a method for treating epilepsy based determining treatment efficacy and providing treatment based on predicted success of the treatment, and Group III. is drawn to a method of analyzing brain activity. While Group I. and Group II. are classified in the same class and subclass, they claim recognized divergent subject matter of using the wavelet transform in different way, specifically in Group I. to determine if an abnormal state exists, and in Group II. to determine the efficacy of various treatments. The invention of Group III. involves predicting abnormal brain activity and does not involve the limitation of treatment found in Groups I. and II..

The Applicant argued the combination/ subcombination restriction as set forth in MPEP 806.05 (c)(II) is improper, but the restriction is based on subcombinations usable together as set forth in MPEP 806.05(d), hence the Examiner is not commenting further on the combination/ subcombination arguments of the Applicant.

While identifying the claims as species is a proper way to identify subject matter (MPEP 809.02(a)(B)), the Examiner has reviewed and modified the species restriction. Relative to

physiological activity, based on the discussion in the specification of the sensor combinations, the Group I. claims associated with electrical, chemical and thermal physiological activity will be prosecuted (claims 36-39 and 41-42). Relative to the restriction based on disease, the Applicant's election being epilepsy, the Group I. claims deemed to read on the elected subject matter will be prosecuted (claims 40, 46 and 49).

In summary, claims 35-46 and 49 are being prosecuted and claims 47, 48 and 50-60 are withdrawn from consideration being drawn to a non-elected invention.

***Response to Amendment filed 3/3/03***

2. The rejections of record are moot since all claims related to this action have been cancelled. A new rejection of record for the newly submitted claims is established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 112***

3. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 42, "the pulses of electrical stimulation" lack antecedent basis.

Claim 42 is unclear because claim 42 limits the electrical stimulation to pulses and depends on independent claim 37, but claim 37 relates to chemical activity not electrical activity.

Claim 42 is unclear because claim 42 claims administering electrical stimulation pulses, but the claims on which claim 42 depend, claims 36, 37 or 38, sense activity and do not administer stimulation.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. Claims 35-40, 43, 45, 46 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Dorfmeister et al. (US 5995868). Dorfmeister et al. disclose a system that monitors electrical signals representative of a subject's brain activity and analyzes the signals using a processor (12) to enable treatment (col. 4 @ 64 – col. 5 @ 6; col. 8 @ 37-48). The treatment can be electrical stimulation, cooling or a medicament (col. 6 @ 50-62; col. 9 @ 10-27; col. 32 @ 45-58). Additional sensors provide data on the condition of the patient, including chemical and thermal sensors (col. 9 @ 40-67; col. 13 @ 18-28 and 55-59). Signal processing includes adaptive analysis of waveform characteristics such as wavelet transform analysis (col. 5 @ 6-10; col. 16 @ 32-41). Coherence analysis, also known as cross correlation analysis, is disclosed for use with wavelet transform (col. 17 @ 18-20; col. 23 @ 55 – col. 24 @ 3).

***Claim Rejections - 35 USC § 103***

5. Claim 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Ward et al. (US 5978702). As discussed in paragraph 4 of this action, Dorfmeister et al. disclose the claimed invention except for the treatment being electrical pulses (claim 41) and the medicament being a drug such as dopamine agonist (claim 44).

As to the pulses, Ward et al. disclose electrical stimulation techniques for treating epilepsy and teach that it is known to use stimulation pulses to increase medicament efficacy (col. 8 @ 44-46; col. 9 @ 10-12). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system that analyzes signals representative of a subject's brain activity as taught by Dorfmeister et al., with the inclusion of

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stimulation pulses as taught by Ward et al. to provide a proven means to optimize the impact of the medicament so the seizure is arrested as soon as possible.

As to the drug, Ward et al. disclose drug infusion techniques for treating epilepsy and teach that it is known to use a dopamine agonist to alter the neural environment of the brain (col. 8 @ 37-43 and Table I.). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system that analyzes signals representative of a subject's brain activity as taught by Dorfmeister et al., with the inclusion in the medicament delivery system of a dopamine agonist as taught by Ward et al. to provide a specific drug that will alter the neural environment of the brain and alleviate the neural symptoms, specifically seizures.

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of King et al. (US 5925070). As discussed in paragraph 4 of this action, Dorfmeister et al. discloses the claimed invention except for the charge balance of the current pulse sequence being ordered and maintained by dynamic feedback.

King et al. disclose controlling the locus of excitation of electrically excitable tissue and teach that it is known to provide tissue stimulation based on dynamic feedback to maintain charge balance (col. 10 @ 43-65) to enable optimum tissue stimulation. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system that analyzes signals representative of a subject's brain activity as taught by Dorfmeister et al., with the pulse sequencing using charge balancing as taught by King et al. to provide optimum tissue stimulation by ensuring, with charge balancing, that the tissue is not damaged or destroyed by the imbalance in the charge field during the treatment periods.

***Specification/ Information Disclosure Statement***

7. The specification contains a reference section. A reference section is not an accepted heading in a specification. Removal of the reference section and inclusion, if necessary, in an Appendix is suggested.

**Content of Specification**

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.  
  
Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.
- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
  - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
  - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and

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problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the



World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

- (k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

As to an Information Disclosure Statement, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

#### *Statutory Basis*

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Other Prior Art Cited*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5314458 to Najafi et al. teaches charge balancing. US 6594524 to Esteller et al. teaches coherence and cross-correlation (col. 14 @ 60-64; col. 27 @ 55-59; col. 30 @ 10-17).

#### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FO*  
*8-4-03*

*Angela D. Sykes*

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